

## **REMARKS**

Claims 13-15, 17-21, 26-31 and 34-40 are pending herein.

### **The Amendments**

Claim 17 has been amended to incorporate limitations of claim 34. Support is found, e.g., in Figure 1. Claim 13 has been amended to depend on claim 17 and to specify that the coding sequence is oriented so as to produce antisense RNA. Support is found, e.g., at page 7, first full paragraph. Claim 16 has been cancelled as redundant. Withdrawn claim 20 has been amended to be dependent on claim 17 and to specify a plant rather than a seed. New claim 40 dependent on claim 20 has been added to claim a seed of a plant of claim 20. Withdrawn claim 21 has been amended to specify oil from a seed of claim 40. Withdrawn claim 26 has been amended to be dependent on claim 17. Withdrawn claims 27 and 30 have been amended to specify that the construct inserted into the plant genome is heterologous, and reference to the promoter has been deleted. Withdrawn claim 29 has been amended to add broccoli to the list of plants. Support is found at page 31. Withdrawn claim 34 has been amended to recite the same limitations as amended claim 17. New claim 39 has been added to be ultimately dependent on claim 34 and to specify the limitations of amended claim 29. No new matter has been added.

### **The Restriction Requirement**

A Restriction Requirement was made as follows:

I. Claims 13-14, 16-18 and 20, drawn to plants and seeds having increased or altered production of gamma tocopherol by transformation with gamma tocopherol methyl transferase and plants and methods thereby, classified in class 800, subclass 288 for example.

II. Claims 17-18, 20-21 and 27-36, drawn to plants and seeds having increased or altered production of alpha tocopherol by transformation with gamma tocopherol methyl transferase and methods thereby, classified in class 800, subclass 28, for example.

III. Claims 15, 19, 21 and 26, drawn to oil from seeds, classified in class 424, subclass 776 for example.

However, the Office Action states that during a telephone conversation with Applicant's previous representative, Sara Vinarov on November 9, 2006, a provisional election was made to prosecute the invention of Group I, claims 13-14, 16-18, and 32-33, a different set of claims than were specified in the Restriction Requirement. These were the claims that, in fact were examined.

The Restriction Requirement is traversed on the ground that the elected claims are not being examined. Further, the Restriction Requirement is improper in including claims 18 and 20 in both Groups I and II.

The Office Action states that Group I claims are classified in class 800, subclass 288, and Group II claims are classified in class 800, subclass 28.

The Definition of Class 800, subclass 288, reads as follows:

Class 800: MULTICELLULAR LIVING ORGANISMS AND UNMODIFIED PARTS THEREOF AND RELATED PROCESSES:

subclass 278: Method of Introducing A Polynucleotide Molecule Into or Rearrangement of Genetic Material Within A Plant or Plant Part:

sub-subclass: 288: . Nonplant protein is expressed from the polynucleotide.

No subclass 28 under class 800 appears to exist. Thus, the Restriction Requirement fails to indicate a distinction between Groups I and II that would place a searching burden on the Office.

Although the Office Action states that "the different inventions are the transformed plants and seeds having increased or altered gamma tocopherol of Group I and the transformed plants and seeds having increased or altered alpha tocopherol of Group II drawn to plants having different phenotypes," this does not appear to be the case. For example, claims 17 and 18 of Group II do not appear to be drawn to different

phenotypes than claims 13-14, 16, 17, 18 or 20 of Group I. All the foregoing claims are drawn to transgenic plants or seeds that have an altered profile of tocopherols.

Withdrawal of the Restriction Requirement and examination of all pending claims is respectfully requested.

#### **Request for Rejoinder of Withdrawn Claims**

In view of the above arguments and the amendments presented herein, rejoinder of the withdrawn claims is respectfully requested. The claims of Group III to oil from seeds of the transformed plants claimed in Groups I and II incorporate all the limits of the claims of Groups I and II from which they depend, and therefore are properly rejoined upon a determination of allowability of the claims from which they depend. With respect to withdrawn claims 27-36 drawn to methods for making transformed plants described herein, it is noted that these claims were specified as claims of Group II, which has been shown above not to have been properly restricted from Group I. As to claims 37-40, it is noted that no restriction requirement was applied to these claims. It is therefore respectfully requested that all withdrawn pending claims be rejoined and examined.

#### **The Rejections Under Section 112, first paragraph**

Claims 13-14, 17-18 and 32-33 have been rejected under 35 U.S.C.112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action states:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to transgenic plants and seeds that have been altered to have gamma tocopherol as the dominant species of tocopherol and plants altered by transformation with a polynucleotide encoding a polypeptide having at least 35% or 61% sequence identity to SEQ ID NO: 4.

Applicants describe polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 3 encoding polypeptides SEQ ID NO: 2 and SEQ ID NO: 4 respectively.

Applicants do not describe any transgenic plants altered to produce gamma tocopherol as the dominant tocopherol species in transformed seeds other than transgenic plants comprising SEQ ID NO: 1 or 3; or any polynucleotides encoding SEQ ID NO: 2 or 4 other than SEQ ID NO: 1 and 3.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus" See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43, USPQ2d 1398, 1406 (Fed. Cir. 1997). [Emphasis added.]

Applicants fail to describe a representative number of polynucleotide encoding polypeptides having at least 35% or 61% sequence identity to SEQ ID NO: 2 or 4 possessing gamma methyl tocopherol transferase activity. Applicants only describe SEQ ID NO: 1 and 3 encoding SEQ ID NO: 2 and 4. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of gamma methyl tocopherol transferases. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for gamma methyl tocopherol transferase activity, it remains unclear what features identify a gamma methyl tocopherol transferase. Since the genus of gamma methyl tocopherol transferases has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Sequences that have at least 35% or 61% sequence identity to SEQ ID NO: 4 or 2 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 4 or 2, as well as sequences encoding proteins having no known gamma methyl tocopherol transferase activity, of which Applicant are not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of gamma methyl tocopherol transferases encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

It is submitted that the claims as amended herein meet the written description and enablement requirements of Section 112, first paragraph. The consensus sequences provided in Figure 1 and the limitations incorporated into the amended claims to recite particular structural features (consensus sequences), **meet the second prong of the *Eli Lilly* test.**

Further, the claims recite functional as well as structural features, and thus exclude inoperative embodiments not having gamma methyltransferase activity.

Moreover, the disclosure, beginning with the first full paragraph on page 9 through the last full paragraph of page 10, fully describes and enables the identification of other plants having the claimed sequences capable of providing altered tocopherol profiles in transformed plants. In addition, Table 2 on pages 30-31 provides a list of specific plants and the altered tocopherol profiles in these plants achievable by insertion of the nucleic acid sequences described and claimed herein.

In view of the foregoing arguments and amendments, it is respectfully requested that the rejections under Section 112 be withdrawn.

Although the rejection has not been applied to withdrawn claims 27-31, for which rejoinder has been requested, it is submitted that these claims also recite structural features that meet the second prong of the *Eli Lilly* test.

### **The Obviousness-Type Double Patenting Rejection**

Claims 13-14, 16-18 and 32-33 have been rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-6 and 9-11 of U.S. Patent No. 6,642,434. The Office Action states:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the transgenic plants and seeds comprising a gamma tocopherol methyl transferase gene of the instant application where gamma tocopherol is the most abundant tocopherol

species in transformed seeds is obvious over the transgenic plants and seeds of U.S. Patent 6,642,434 comprising a gamma tocopherol methyl transferase of SEQ ID NO: 1 or 3 having an altered alpha:gamma tocopherol ratio and seeds thereof.

A Terminal Disclaimer is submitted herewith, together with a Statement Under 37 CFR 3.73(b). It is submitted that this Terminal Disclaimer overcomes the rejection, and its withdrawal is respectfully requested.

The undersigned would like to take this opportunity to correct what may be a misunderstanding of the invention as described in the above-quoted language from the Office Action. The presence of a gamma tocopherol methyltransferase gene in a transformed plant results in increased alpha tocopherol rather than increased gamma tocopherol. See, e.g., the last partial paragraph on page 5 of the specification. To produce a plant having increased gamma tocopherol, the gene should be inserted an antisense orientation. See page 7, first full paragraph.

#### **The Rejections Under Section 102**

Claims 17-18 have been rejected under 35 U.S.C.102(e) as being anticipated by U.S. Patent 6,429,356 (Shewmaker et al.) that claims priority to. U.S. Provisional 60/024,145 filed 9 August 1996. The Office Action states:

Patent 6,429,356 teaches altered profile of tocopherols in the seeds of transformed plant (see 2 page attached provisional 60/024,145; pages 23-24; especially page 24 Table 2); and thus the reference teaches all the limitations of Claims 17-18.

Claim 17 has been amended to recite numerous additional limitations not present in the Shewmaker disclosure. Thus it is not anticipated by the reference. Claim 18 is dependent on claim 17 and is therefore also not anticipated by the reference.

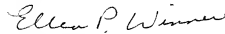
It is noted that claims 13-14, 16 and 32-33 have been deemed free of the prior art given the failure of the prior art to teach or reasonable suggest a transgenic plant or seed comprising SEQ ID NO: 1 or SEQ ID NO: 3; or transgenic plants and seeds that

have been altered to have gamma tocopherol as the dominant species of tocopherol when compared to the wild type plant or seeds.

## Conclusion

All claims pending herein appearing to be in condition for allowance, rejoinder of withdrawn claims and passage to issuance is respectfully requested. This amendment is accompanied by a Petition for Extension of Time (three months) which authorizes the charge of \$510.00 as required under 37 C.F.R. 1.17. A Terminal Disclaimer together with the fee of \$65.00 is also submitted herewith. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount authorized is incorrect, however, please deduct from Deposit Account No. 07-1969 the appropriate fee for this submission and any extension of time required.

Respectfully submitted,



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